DEC 21 2000

K001634

510(k) SUMMARY of Safety and Effectiveness

21 CFR 807.92(c)

I. GENERAL

Prepared 8/26/00

A. Submitted By:
(21 CFR 807.92 (a)(1)

TZ Medical Inc.
15858 S.W. Upper Boones Ferry Rd.
Lake Oswego, Oregon 97035
Fax: 503-639-0239
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B. Contact Person
(21 CFR 807.92(a)(1)

Madalyn C. Duncan
Regulatory Specialist

C. Proprietary Name:
(21 CFR 807.92(a)(2)
Common Name

CardioSentry Event Monitor
(CardioSentry EM)
Cardiac Event Recorder

D. Classification Name:
(21 CFR 880.6250)

Transmitters and Receivers,
Electrocardiograph,

E. Classification:

Class II, Cardiovascular 74 DXH,
CFR 870.2920

II. DEVICE INFORMATION SUMMARY

A. Predicate Device
(21 CFR 807.92(a)(3)

P.H.D. - Personal Heart Device

B. Device Description Summary
(21 CFR 807.92(a)(4)

The "CardioSentry" is a transtelephonic, electrocardiograph recorder and transmitter, used to record heart ECG's and transmit the information over the telephone to an ECG recording machine. The device will be obtained by a patient or individual and activated upon qualification for service when the participant calls a predetermined number. Once the device is activated, the participant may record and transmit their ECG and communicate with cardiac monitoring center.

C. Device Intended Use
(21 CFR 807.92(a)(5)

The device is intended for use by patients or individuals who have or are at risk of having cardiac disease as well as those who have intermittent symptoms indicative of cardiac disease. The device will also be available to individuals who have conditions or take medications which may affect their cardiac

rhythms or health and to individuals who want to monitor their own cardiac ECG.

D. Technological Comparison P.H.D. from Heart Alert
(21 CFR 807.92(a)(6)

The P.H.D (predicate) and the CardioSentry have the same intended use and principles of operation.

Both the P.H.D. and the CardioSentry Event Monitor operate in the same manner and use the same method to record and provide the ECG signal. The frequencies are identical, see attached tables. The devices are purchased by an individual and activated upon qualification for the service. Both device require a designated doctor for the service to be activated. Once the device are activated, the participant may record and transmit their ECG and communicate with the monitoring center.

Summary of Changes:

Both devices are the same size and weight with only minor differences. The FSK (0) and FSK (1) specifications are tightened in the CardioSentry to provide less drift and a more accurate signal. The primary difference was in the volatile memory. The CardioSentry does not require additional batteries to maintain storage of memory. This function has been incorporated into the electronics of the device. The P.H.D. requires an battery to maintain the stored memory.

Characteristics	CardioSentry EM and Service	P.H.D. and Service
1. Physical		
Size	3.3" X 2.1" X 0.375"	3.35" X 2.15" X 0.26
Weight	57 grams (2 oz) with Lithium Cell battery (2430)	30 grams without bather 50 grams with battery
Batteries Backup	3.0 Volt Battery (CR2430) One year None Required	3.0 Volt Battery (CR2430) Appx. One year (CR1220) Appx. 60 days
2. Environmental		
Operating Temperature	10 C Minimum 43 C Maximum	10 C Minimum 40 C Maximum
Storage Temperature	-40 C Minimum 66 C Maximum	-10 C Minimum 60 C Maximum
Relative Humidity	10 % Minimum 90 % Maximum	10% Minimum 95% Maximum
Shock (drop height on all faces, edges, and corners)	36 inches	36 inches
3. Transmission		
Center Frequency	1850 Minimum 1900 Typical 1950 Maximum	1850 Minimum 1900 Typical 1950 Maximum
Deviation	90 Hz/mV Minimum 100 Hz/mV Typical 110 Hz/mV Maximum	90 Hz/mV Minimum 100 Hz/mV Typical 110 Hz/mV Maximum
FSK 0	1875 Hz Typical +/- .05 Hz	1850 Minimum 1900 Typical 1950 Maximum
FSK 1	2345 Hz Typical +/- .05 Hz	2400 Hz Minimum 2450 Hz Typical 2590 Hz Minimum

Characteristics	CardioSentry EM and Service	P.H.D. and Service
4. Electrical		
Impedance (5 Hz)	2.4 M ohm *	100 Mohm Minimum
CMR Ratio	(10 Hz) - 60 dB Minimum	(5 HZ) -60 dB Minimum
Differential Input Signal (AC)/Common Mode Range (AC +DC)	-2.2 mV Peak AC Minimum +2.2 mV Peak AC Maximum	-2.0 mV Minimum +2.0 mV Maximum
Common Mode Voltage/ Differential Range: (AC: +1mV AC @5 HZ)	-1.5 V Minimum +1.5 V Maximum	-0.500V Minimum +0.500V Maximum
Differential Offset (DC +2.2 mV AC)/Differential Range: (DC: +1mV AC @5 HZ)	-200 mV Minimum +200 mV Maximum	-250 mV Minimum +250 mV Maximum
Baseline Reset Time:	1 Second Typical	1 Second (Typical Value)
4. Electrical (continued)		
Bandwidth (+1dB/-3dB)	0.5 Hz Minimum (ref 10 Hz) 30 Hz Maximum (ref 10 Hz)	0.5 Hz Minimum (ref 15 Hz) 30 Hz Maximum (ref 15 Hz)
Resolution (calculated):	19.33 uV	15.6 uV (Typical Value)
Timer Resolution	Not Applicable do not keep track of elapsed time	1 Second Minimum
Timer Accuracy	Not Applicable - No timer	10 Seconds/Month
Recording Period (sampling rate 218 Hz)	30 seconds @ 120 Hz	30 seconds Minimum
Memory Hold Time	200 years Typical**	128 days
Elapsed Time (since first recording)	Not Applicable - No Timer	31 Days

* Meets or exceeds AAMI Standards for this requirement **Storage time needs no battery

III. SERVICE INFORMATION SUMMARY

Monitoring centers house a 24 hour ECG monitoring service. Their purpose is to provide a range of cardiac monitoring modalities, including participant's cardiac event monitoring. The monitoring centers provide support service for participants, patient, physicians, and home health care agencies. Event monitoring is valuable. Qualified participants (enrollees) in the CardioSentry OTC service will derive value and comfort in having their cardiac status monitored under normal everyday activity, such as work, exercise, business, travel or leisure activity.

IV. TESTING SUMMARY
(CFR 807.92(b)(1)

Safety and Effectiveness Testing for the CardioSentry includes:

- Software Verification/Validation
- Verification of the devices functions, programs, and circuitry
- Simulated Use Testing
- AAMI #38 Ambulatory Electrocardiographs - 1994Standards Testing Type 3 device
- IEC 801, Applicable Sections for Type 3 device.

The CardioSentry passed tests identified above and demonstrates that the safety (AAMI #38, Ambulatory Electrocardiographs Standards and IEC #801 Electromagnetic Standards testing) and efficacy are substantially equivalent to the testing performed for the P.H.D.

V. CONCLUSIONS
(CFR 21 897.92 (b)(3)

Based on the test data , the CardioSenty is a safe and effective means of recording and transmitting a participants ECG to a cardiac monitoring center.
There are no adverse safety and effectiveness implications from the device or its operation when used as intended.

The test results demonstrate that the device is as safe and as effective as the predicate. device. The CardioSentry performs as well as the legally marketed P.H.D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

Ms. Madalyn C. Duncan
Regulatory Specialist
TZ Medical, Inc.
15858 S.W. Upper Boones Ferry Road
Lake Oswego, OR 97035

Re: K001634
Trade Name: Cardiosentry Event Monitor, Model 8470-01
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: August 28, 2000
Received: September 26, 2000

Dear Ms. Duncan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX II

510(k) Number (if known) K001634
Device Name: CardioSentry Event Monitor (CardioSentry EM)

Device Description/Indications for Use:

The "CardioSentry" Event Monitor is a transtelephonic, electrocardiograph recorder and transmitter, used to record heart ECG's and transmit the information over the telephone to an ECG recording machine. The device will be obtained by a patient or individual and activated upon qualification for service when the participant calls a predetermined number. Once the device is activated, the participant may record and transmit their ECG and communicate with cardiac monitoring center.

This device may be helpful for patients who have:

Skipped beats;
Pounding heart (palpitations);
Racing heart rate (tachycardia);
History of abnormal rhythm (arrhythmias); or
Lightheadedness or faintness.

Contraindications:

This device should not be used by the participant or their assistant who are unable to:

Read the directions;
Hold the device steady on their chest;
Hear the recording beep signal;
Operate a telephone or the device; or
Speak or understand English.

Due to possible seriousness of abnormal heart rhythms, the participant should consult their physician if they have:

Coronary Heart Disease;
Valvular heart disease;
Chest pain (angina);
Heart failure;
Loss of consciousness and/or fainting; or
Pacemaker or implanted defibrillator.

Such patients must have written authorization from their physician prior to beginning the program.

The CardioSentry cannot predict or diagnose a heart attack and is not a substitute for medical attention. This device is for monitoring purposes only and has no therapeutic value. It provides the individual access to cardiac monitoring services.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence

Of CDRH, Office OF Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

Over-The-Counter Use ✓
(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K001634